Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PETER K. LAW

MAILED

AUG 28 2002

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal No. 2001-2190
Application No. 09/005,034

ON BRIEF[1]

Before ADAMS, MILLS and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 20-25 and 27-32, which are all the claims pending in the application.

Claims 20 and 28 are illustrative of the subject matter on appeal and are reproduced below:

20. A method for treating a body part of a subject, comprising (a) culturing myogenic cells to form a composition of cells and then (b) administering said composition into the body part such that the cosmetic appearance of the subject is altered.

[1] In accordance with 37 CFR 1.194(c), the Board decided that an oral hearing was not necessary in this appeal. Therefore, this appeal was decided on Brief.

28. In a method for augmenting a body part with plastic surgery of the body part by implantation of silicone, the improvement consisting of replacing injection of silicone with multiple transverse injection of a composition that comprises myogenic cells.

The references relied upon by the examiner are:

DiMario et al. (DiMario), Myoblast Transfer into Skeletal Muscle, Unresolved Questions of New Muscle Formation for Injected Myogenic Cells, in Neuromuscular Development and Disease, Vol. 2, pp. 329-341, (Alan M. Kelly et al. eds., Raven Press) (1992)

Morgan et al. (Morgan), "Formation of skeletal muscle in vivo from the mouse C2 cell line," J. Cell Science, Vol. 102, pp. 779-787 (1992)

Hoffman, "Myoblast Transplantation: What's Going On?," Cell Transplantation, Vol. 2, pp. 49-57 (1993)

Coovert et al. (Coovert), "Gene therapy for muscle diseases," Current Opinion in Neurology, Vol. 7, pp. 463-470 (1994)

GROUND OF REJECTION

Claims 20-25 and 27-32[2] stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure.

We reverse.

DISCUSSION

To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the

[2] The examiner incorrectly included claim 33 as part of this rejection. We note that new claim 33 was included as part of appellant's after final amendment. The examiner, however, did not enter this amendment. See Advisory Action, Paper No. 16. Therefore, as appellant correctly identified (Brief, page 2), pending claims 20-25 and 27-32 are the subject of the present appeal. We note that the examiner agreed with this statement. See Answer, page 2, "[t]he statement of the status of the claims contained in the brief is correct." Accordingly, claim 33 is not before this Merits Panel for review, and any reference to this claim has been omitted herein.

application was filed without undue experimentation. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). We note, however, that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

To assist the fact finder in meeting his initial burden of setting forth a reasonable explanation as to why he believes the scope of the claimed invention is not adequately enabled by the description, our appellate reviewing court has outlined a number of factors that should be considered. As set forth in In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988), the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. We will consider the

examiner's conclusion that the specification fails to enable the claimed invention with this precedent in mind.

The examiner finds (Answer, page 7), "[t]he sole reference to cosmetic usage in the disclosure is found in the paragraph bridging pages 22-23." For clarity, this section of the specification (bridging paragraph, pages 22-23) is reproduced below:

> C. COSMETIC USAGE
>
> In a broader sense, the cell therapy concept can significantly contribute to the field of plastic surgery. With cell therapy, implantation of silicone could be avoided. The use of myoblasts and/or fat cells could be used in a much more natural way to replace silicone injections for facial, breast and hip augmentation. Modified adipose tissue involving mixing and/or hybridization of myoblasts and fat cells can be used to control size, shape and consistency of body parts. Since muscle cells do not break down as easily as fat cells, good results may be long-lasting. Today, body builders are in search of increasing muscle mass and function at the right prices. The use of myoblast transfer to boost muscle mass is a natural solution.

According to the examiner (id.), "[t]he remainder of the disclosure teaches myoblast transfer for treatment of Duchenne muscular dystrophy [(]DMD[)] or infantile facioscapulohumeral dystrophy (IFSH), both conditions accompanied by deteriorating muscle tissue. There is no guidance provided as to how one of skill in the art could apply those teachings to cosmetic alteration of non-diseased body parts." In this regard, we note that only two of appellant's claims (claims

21[3] and 30[4]) include, by way of a Markush grouping, a limitation to a "non-diseased body part." Nevertheless, for the reasons that follow, we find that the examiner failed to establish a prima facie case of non-enablement.

With reference to Coovert and Hoffman, the examiner finds (Answer, page 5), "[t]he art teaches that when cultured myoblasts are injected into skeletal muscle in mice, some of the cells can contribute to the formation of new muscle in vivo [and a] ... partial restoration of dystrophin levels in mice." However, the examiner finds (id.), "[t]he art does not teach that the cosmetic appearance of a human [or mouse] body part can be altered by injection of myoblasts into that body part ... [but instead] teaches that human transfer has not been successful or at best that the results of human transfer have been controversial..." [emphasis added].

In response, appellant argues (Reply Brief, page 3), Coovert teach "that myoblast transfer in humans suffering from muscular dystrophy has not been successful ... [however] [a]ppellant already has shown that myoblast transfer therapy according to the present invention does work in diseased muscle...." According to appellant (Brief, pages 7-11), the specification provides guidance that overcomes the failures of the prior art, which did not use appellant's methodology.

---

[3] Claim 21. A method as described in claim 20, wherein said body part is a face, breast, hip or non-diseased muscle.
[4] Claim 30. A method as described in claim 28, wherein the body part is a face, breast, hip, or non-diseased muscle.

We note that, on this record, the examiner provides no evidence or argument to dispute appellant's assertion that "myoblast transfer therapy according to the present invention does work in diseased muscle." Nevertheless, the examiner, however, is not persuaded by appellant's arguments. According to the examiner (Answer, page 9), "all of the teachings [appellant] referred to are for treatment of diseased muscles associated with DMD or IFSH. None are referenced for cosmetic alteration of a non-diseased body part." According to the examiner (id.), appellant's specification does not provide sufficient guidance for treating non-diseased tissues. In this regard, the examiner finds (Answer, page 6), with reference to DiMario, that "the growth or regenerative state of the muscle into which myogenic cells are transferred affects the degree to which donor myoblasts contribute to new muscle formation, with incorporation occurring in regenerating muscle to a much greater extent than in normal uninjured or non-diseased muscle...." Therefore the examiner concludes (id.), "it is unclear how donor myoblasts could be used to alter the cosmetic appearance of non-diseased muscle."

In response appellant argues (Reply Brief, page 6), DiMario "never state that myoblast transfer would not work with non-diseased muscle. Instead, DiMario et al. provide only that 'regenerating muscle provides a better environment for myoblast transfer and incorporation into new and existent muscle fibers than growing musculature...'." The examiner offers no response to appellant's argument. Absent the examiner's reliance on DiMario, the examiner provides no factual evidence to support her position that the examples disclosed

in appellant's specification for the treatment of diseased muscle[5] could not be extrapolated to the cosmetic alteration of a non-diseased body part.

Considering the evidence presented for our review, it is our opinion that the examiner failed to set forth the evidence necessary to establish that appellant's examples of treating diseased muscle does not support claims drawn to cosmetic alteration. Stated differently, the examiner failed to set forth the evidence necessary to establish a prima facie case of non-enablement.

The examiner also finds (Answer, page 6) that claims 21 and 30 are "drawn to alteration of the cosmetic appearance of a body part selected from a face, breast, hip, and non-diseased muscle." According to the examiner (id.), "human breast is composed of adipose tissue and the human hip is composed of bone. ... Conventional wisdom teaches that myoblasts only fuse with myoblasts (i.e. muscle cells). The art does not teach fusion of myoblasts with adipocytes or osteocytes." Therefore the examiner concludes (id.), "it is unclear how

---

[5] With regard to the treatment of diseased muscle, we note that appellant is a co-inventor of Law et al., U.S. Patent No. 5,130,141 ('141), drawn to compositions for and methods of treating muscle degeneration and weakness. Claim 1 of '141 is reproduced below:

1. A method of treating muscle degeneration and weakness in a host, comprising the steps of:
culturing genetically normal myogenic cells from donors to produce a supply of the myogenic cells comprising myoblasts, myotubes, and young muscle fiber cells;
administering a therapeutically effective dosage of an imunosupressant to the host; and
thereafter selecting and administering from the said supply a therapeutically effective dosage of myogenic cells to at least one myopathic muscle of the host,
whereby muscle functions, locomotive patterns, and respiratory functions are improved.

administration of myoblasts to breast tissue or to a hip could be used to alter the cosmetic appearance of the body part."

In response, appellant argues (Reply Brief, page 4), "the specification provides, '[i]njected muscles include those in the neck, shoulder, back, chest, abdomen, arms, hips, and legs' (Specification at page 12, lines 10-12) ... there is muscle tissue in the breast, as well as areas proximate the hip bone, with which administered myoblasts can fuse." The examiner offers no response to appellant's argument. From appellant's argument, it seems clear that while other cell types (e.g., adipocytes and osteocytes) may be present in the area of injection, muscle is also available in each area to which myoblasts can fuse when administered according to the claimed invention. In our opinion, the examiner failed to present the evidence necessary to support a finding that the claimed invention is not enabled for the claimed method wherein the body part is breast or hip.

With reference to Morgan, the examiner finds (Answer, page 7), "[t]he art teaches that injection of proliferating undifferentiated muscle cells results in the formation of tumors at the site of injection.... Detailed teachings are required in the disclosure to overcome the teaching of tumor formation."

In response, appellant argues (Reply Brief, pages 4-5), Morgan "only teach that tumor formation readily occurs when myoblasts are administered to freeze-killed muscle ... [t]he present invention does not require the administering of myoblasts to freeze-killed muscle." Appellant also argue (Reply Brief, page 5), Morgan "do not teach that tumor formation occurs at the site of injection, after

administering myoblasts to living muscle tissue." In addition, appellant points out (Reply Brief, page 6) that while Hoffman recognizes the possibility clearly exists no tumors have been observed to date in humans who have been administered myoblasts.

The examiner offers no response to this argument. Therefore, we are compelled to agree with appellant (Reply Brief, page 5) that "the [e]xaminer has failed to meet ... [her] burden of providing non-enablement in this context." Furthermore, we caution the examiner against confusing the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug. See Scott v. Finney, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994) (testing for safety and effectiveness "is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings").

For the reasons discussed above, it is our opinion that the examiner failed to present the evidence necessary to establish a prima facie case of non-enablement. Accordingly, we reverse the rejection of claims 20-25 and 27-33 under 35 U.S.C. § 112, first paragraph.

OTHER ISSUES

We encourage the examiner to review the '141 patent to determine whether the claims recited therein would give rise to an obviousness-type double patenting rejection of the appealed claims.

In addition, we note the examiner's obviousness-type double patenting rejection (Paper No. 6, page 6) of claims 20-27 over claims 5-11 of Application No. 09/005,035, now United States Patent No. 6,261,832 ('832). We further note the examiner's statement (Paper No. 11, page 8), recognizing "applicant's intention to file a terminal disclaimer in the event the claims conflicting with claims 5-11 of copending Application No. 09/005,035 are allowed. This rejection is held in abeyance until such time." On this record, it is unclear whether the examiner intended to withdraw this rejection. In this regard, we remind the examiner as set forth in Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 663, 231 USPQ 649, 651-652 (Fed. Cir. 1986) (citation omitted):

> When an examiner fails to mention a rejection in his final action, it has been dropped by the examiner and needs no further response by the applicant. On appeal, only those grounds of rejection which have been made in the final rejection and commented upon in the examiner's answer to brief are considered by the Board. All rejections previously made and not continued in the final rejection are considered as withdrawn. It is not necessary for the examiner to make any specific statement to that effect.

This obviousness-type double patenting rejection was not commented upon in the Answer, therefore, it is considered withdrawn. Accordingly, we encourage the examiner to consider the '832 patent to determine if the claims therein give rise to an obviousness-type double patenting rejection of the appealed claims. In this regard, we note that any further communication from the examiner that contains a rejection of the claims should provide appellant with a full and fair opportunity to respond.

SUMMARY

The rejection of claims 20-25 and 27-32 under 35 U.S.C. § 112, first paragraph is reversed.

REVERSED

Donald E. Adams)
Administrative Patent Judge)
)
)
Demetra J. Mills) BOARD OF PATENT
Demetra J. Mills)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
Eric Grimes)
Administrative Patent Judge)

DA/dym

Colin G. Sandercock
Heller Ehrman White & McAuliffe LLP
1666 L Street N.W.
Suite 300
Washington DC 20006